
**Izmenjevalniki toplote in vlage ter filtri dihalnih sistemov za dihalne pline - 1. del:
Splošne zahteve (ISO/DIS 9360-1:2026)**

Heat and moisture exchangers, and breathing system filters for respired gases - Part 1:
Common requirements (ISO/DIS 9360-1:2026)

Anästhesie- und Beatmungsgeräte - Wärme- und Feuchtigkeitsaustauscher und
Atemschutzfilter (HMEF) zur Anfeuchtung von Atemgasen beim Menschen - Teil 1:
Allgemeine Anforderungen (ISO/DIS 9360-1:2026)

Titre manque — Partie 1: Titre manque

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and resuscitation equipment
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DRAFT International Standard

ISO/DIS 9360-1

Heat and moisture exchangers, and breathing system filters for respired gases —

Part 1: Common requirements

ICS: 11.040.10

ISO/TC 121/SC 2

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Foreword

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ISO 9360-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airway devices and related equipment*.

ISO 9360 consists of the following parts, under the general title *Breathing system filters for anaesthetic and respiratory use*:

- Part 1: Common requirements
- Part 2: Measurement of moisture loss
- Part 3: Measurement of filtration performance

These parts technically revise and replace ISO 9360-1:2000, ISO 9360-2:2001, ISO 23328-1:2008 and ISO 23328-2:2009.

These parts are a combination of the above standards with new and modified requirements, in particular:

- Part 1 combines requirements from ISO 9360-1:2000 and ISO 23328-2:2009
- Part 2 combines requirements from ISO 9360-1:2000 and ISO 9360-2:2001.
- Part 3 are requirements from ISO 23328-1:2008.

Specific changes include:

- layout now follows the format of ISO 18190:202x; and references clauses from ISO 18190
- Colour coding requirements were added to distinguish between *HMEs* and *BSFs*

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Introduction

The gases generally available for medical use lack sufficient moisture to be physiologically acceptable to the respiratory tract of patients. *Heat and moisture exchangers (HME)* are used to raise the water content and the temperature of the gas delivered to the respiratory tract of spontaneously and non-spontaneously breathing patients. *HMEs* are intended to form part of a ventilator breathing system. *HMEs* are primarily placed between the patient interface (e.g. Tracheal or Tracheostomy Tube) and the anaesthesia or ventilator breathing set. *HMEs* are also intended for use with tracheostomy tube where the *HME* is not designed to be connected to a anaesthesia or ventilator breathing set.

Breathing system filters (BSF) are used to reduce particulates, including microorganisms, in gases delivered to and exhaled from patients. *BSFs* are intended to form part of a ventilator breathing system. *BSFs* may be placed between the patient interface and the anaesthesia or ventilator breathing set or placed between the anaesthesia or ventilator breathing set and the anaesthesia or ventilator machine. *BSF* are exposed to various levels of humidity during clinical use.

Many devices combine the characteristics of both an *HME* and a *BSF* in one combined device, called an *HMEF*. *HMEs* and *HMEFs* are only intended for use between the patient interface and the anaesthesia or ventilator breathing set.

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